GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:274
ANSWERED ON:20.11.2002
SAFETY OF NIMESULIDE USAGE
GADDE RAMAMOHAN;M.V.V.S MURTHI;YEMPARALA VENKATESWARA RAO

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the attention of the Government has been drawn towards the news-item captioned `Nimesulide, the popular fever drug is considered to be unsafe` appearing in Times of India, dated October 10, 2002;

(b) if so, the details thereof;

(c) whether the Government have conducted any inquiry in this regard;

(d) if so, the outcome thereof; and

(e) the steps taken/proposed to be taken by the Government in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) Yes, Sir. The subject news item primarily relates to non-steroidal anti-inflammatory drug (NSAID) Nimesulide which is reported to be used in about 50 countries including India and is indicated for acute pain/inflammation and fever. In India Nimesulide (100mg) tablet was approved in 1995 and in 1996 Nimesulide suspension was approved for children. Nimesulide is a prescription drug in India.

No serious hepatotoxicity in adults or children have been reported to the regulatory agencies in the country. Also, neither the Indian Academy of Paediatricians or any Paediatrician has so far reported any serious side effect in children treated with Nimesulide formulation.

(c) to (e) As a part of ongoing review exercise, a review is being undertaken by expert committee (Sub-Committee of DTAB) to examine safety aspects of Nimesulide. As regards the use of Nimesulide in children, the expert committee was of the view that immediate opinion of at least 20 well known paediatricians across the country may be obtained alongwith the information available from Adverse Drug Reaction centers.